

Safety Data Sheet

acc. to OSHA HCS

Printing date 01/18/2018

Reviewed on 01/05/2018

1 Identification

- **Product identifier**
- **Trade name:** Neutral Protease AF GMP Grade from Clostridium histolyticum
- **Article number:** N0003553
- **CAS Number:** 9001-92-7
- **EC number:** 232-642-4
- **Index number:** 647-014-00-9
- **Application of the substance / the mixture** Laboratory chemicals
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Nordmark Arzneimittel GmbH & Co. KG
Pinnauallee 4
D-25436 Uetersen
Tel.: +49 4122 712-0
FAX.: +49 4122 712-220
sicherheitsdatenblatt@nordmark-pharma.de
- **Information department:** Product Safety department Tel.: +49 4122 712 242
- **Emergency telephone number:**
Medical Emergency Information in case of poisoning:
Poison Information Center Göttingen - Phone: +49 (0) 551 19240
(advisory service in German or English language)



2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS08

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

- **Label elements**
- **GHS label elements**
The substance is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS07, GHS08
- **Signal word** Danger
- **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause respiratory irritation.
- **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapors/spray

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Wash thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Wear protective gloves / eye protection / face protection.
[In case of inadequate ventilation] wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Call a POISON CENTER/doctor if you feel unwell.
Specific treatment (see on this label).
If skin irritation occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
Take off contaminated clothing and wash it before reuse.
Store in a well-ventilated place. Keep container tightly closed.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 1
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = *1
Fire = 0
Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** PBT - assessment not available.
- **vPvB:** vPvB - assessment not available.

3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**
9001-92-7 Proteinase
- **Identification number(s)**
- **EC number:** 232-642-4
- **Index number:** 647-014-00-9
- **Description:**
- **MW:** ca. 34000

4 First-aid measures

- **Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
Remove contaminated clothing immediately.
- **After eye contact:**
Rinse opened eye for several minutes under running water. Remove present contact lenses, if easy to do, and continue rinsing. Consult ophthalmologist In case of complaints.

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- **After swallowing:**
Wash out mouth. Drink plenty of water and supply fresh air. Consult doctor if you feel unwell.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

* 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂ extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture**
Formation of dangerous gases or vapours is possible in case of fire.
In case of fire, the following can be released:
Carbon monoxide and carbon dioxide
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

* 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective clothing.
Ensure adequate ventilation
Avoid contact with the eyes and skin.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
Dispose contaminated material as waste according to item 13.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

* 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of dust.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store at +2 to +8 °C
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed and store in dry conditions.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.

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- **Additional information:** *The lists that were valid during the creation were used as basis.*
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
*Keep away from foodstuffs, beverages and feed.
 Store protective clothing separately.
 Immediately remove all soiled and contaminated clothing.
 Avoid contact with the eyes and skin.
 Wash hands before breaks and at the end of work.*
- **Breathing equipment:**
*Short term filter device:
 Filter P2*
- **Protection of hands:**
*Protective gloves
 The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
 Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/
 the chemical mixture.
 Selection of the glove material on consideration of the penetration times, rates of diffusion and the
 degradation*
- **Material of gloves**
*The selection of the suitable gloves does not only depend on the material, but also on further marks of
 quality and varies from manufacturer to manufacturer.*
- **Penetration time of glove material**
*The exact break through time has to be found out by the manufacturer of the protective gloves and has to be
 observed.*
- **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are
 suitable:**
*Natural rubber, NR
 Nitrile rubber, NBR*
- **Eye protection:** *Safety glasses*
- **Body protection:** *Protective work clothing*

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	<i>lyophilisate</i>
Color:	<i>beige to brown</i>
Odor:	<i>Odorless</i>
- **pH-value:** *no information available*
- **Change in condition**

Melting point/Melting range:	<i>no information available</i>
Boiling point/Boiling range:	<i>no information available</i>
- **Flash point:** *Not applicable.*
- **Flammability (solid, gaseous):** *Product is not flammable.*
- **Danger of explosion:** *Product is not explosive. However, formation of explosive dust-/air
 mixtures are possible.*
- **Density:** *no information available*
- **Solubility in / Miscibility with**

Water:	<i>Soluble.</i>
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· **Other information** No further relevant information available.

* 10 Stability and reactivity

- **Reactivity** No further relevant informations available
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
Denaturation of proteins by strong heating.
- **Possibility of hazardous reactions**
As the product is supplied it is not capable of dust explosion; however enrichment with fine dust causes risk of dust explosion.
- **Conditions to avoid thermal decomposition:** protein denaturation
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** In case of fire: See Section 5

* 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:**
Sensitization possible through inhalation.
Sensitization possible through skin contact.
- **Additional toxicological information:**
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)** Substance is not listed.
- **NTP (National Toxicology Program)** Substance is not listed.
- **OSHA-Ca (Occupational Safety & Health Administration)** Substance is not listed.

* 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow product to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:**
Disposal of uncleaned packagings must be made according to official regulations in the same manner as the product.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- | | |
|--|--|
| · UN-Number
· DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name
· DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es)
· DOT, ADN
· Class | Void |
| · ADR, IMDG, IATA
· Class
· Label | Void
- |
| · Packing group
· DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards:
· Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | Not dangerous according to the above specifications. |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Section 355 (extremely hazardous substances):** Substance is not listed.
- **Section 313 (Specific toxic chemical listings):** Substance is not listed.
- **TSCA (Toxic Substances Control Act):** Substance is listed.
- **Proposition 65** Substance is not listed.
- **Chemicals known to cause cancer:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for females:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for males:** Substance is not listed.
- **Chemicals known to cause developmental toxicity:** Substance is not listed.
- **Carcinogenicity categories**
- **EPA (Environmental Protection Agency)** Substance is not listed.
- **TLV (Threshold Limit Value established by ACGIH)** Substance is not listed.

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- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Substance is not listed.
- **GHS label elements**
The substance is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS07, GHS08
- **Signal word** Danger
- **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause respiratory irritation.
- **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapors/spray
Wash thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Wear protective gloves / eye protection / face protection.
[In case of inadequate ventilation] wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Call a **POISON CENTER/doctor** if you feel unwell.
Specific treatment (see on this label).
If skin irritation occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
If experiencing respiratory symptoms: Call a **POISON CENTER/doctor**.
Take off contaminated clothing and wash it before reuse.
Store in a well-ventilated place. Keep container tightly closed.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Product safety department
- **Contact:** Tel.: +49 4122 712-242
- **Date of preparation / last revision** 01/18/2018 / -
- **Abbreviations and acronyms:**
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
PBT: persistent, bioaccumulative, toxic substance (REACH)
vPvB: very persistent, very bioaccumulative substance (REACH)
REACH: Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
CLP: Regulation on classification, labelling and packaging of substances and mixtures
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health

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TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Resp. Sens. 1: Respiratory sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

. * Data compared to the previous version altered.

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